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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis and Nontuberculous Mycobacteria Drug Susceptibility Testing OMB # 0920-0600 (exp. 5/31/2013), - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the continuing effort to support domestic public health objectives for treatment of tuberculosis (TB), prevention of multi- drug resistance, and surveillance programs, CDC is requesting approval from the Office of Management and Budget to continue data collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacterium Drug Susceptibility Testing. This request includes (a) changing the title of the data collection to "CDC Model Performance Evaluation (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing" to reflect that nontuberculous mycobacteria are no longer included in the test package; (b) replacement of Laboratory Enrollment Form with a Participant Biosafety Compliance Letter of Agreement; (c) revision of the Pre-shipment Email; (d) addition of Instructions to Participants Letter; (e) revision of the MPEP M. tuberculosis Results Worksheet; (f) entering survey results online using a modified data collection instrument; (g) modification of Reminder Email; (h) modification of Reminder Telephone Script; and (i) modification of the Aggregate Report Letter.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with

HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium tuberculosis and Non-tuberculous Mycobacterium Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

By providing an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis strains, laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) samples. The PE samples are sent to participants twice a

year. Participants also report demographic data such as laboratory type and the number of tests performed annually.

There is no cost to respondents to participate other than their time. The total estimated annual burden hours are 156.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Domestic Laboratory	Participant Biosafety Compliance Letter of Agreement	93	2	5/60
	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet	93	2	30/60
	Online Survey Instrument	93	2	15/60

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